Modified FINESSE™ Ultra Breast Biopsy System Driver

510(k) Summary of Safety and Effectiveness
21 CFR 807.92

DEC 27 2010

As required by the Safe Medical Devices Act of 1990, coded under Section 513, Part (I)(3)(A) of the Food, Drug and Cosmetic Act, a summary of the safety and effectiveness information upon which substantial equivalence determination is based as follows:

Submitter Information:

Applicant:	Bard Peripheral Vascular, Inc 1415 West 3rd Street P.O. Box 1740 Tempe, Arizona 85281
Phone:	480-379-2836
Fax:	480-449-2546
Contact:	Cindy Moss, Project Manager, Regulatory Affairs
Date	November 15, 2010

Subject Device Name:

Device Trade Name:	**Modified FINESSE™ Ultra Breast Biopsy System Driver**
Common or Usual Name:	Biopsy Instrument (21 CFR 876.1075, Product Code KNW)
Classification:	Class II
Classification Panel:	Gastroenterology/Urology

Predicate Device:

- FINESSE™ Ultra Breast Biopsy System (K093068, cleared November 10, 2009), manufactured by Bard Peripheral Vascular, Inc.

Device Description:

The subject device, the modified FINESSE™ Ultra Breast Biopsy System Driver, is a non-sterile, self-contained, handheld, reuseable, electro-mechanical vacuum-assisted breast biopsy device that utilizes a rechargeable lithium-ion battery. The driver is designed to operate safely when used with the FINESSE™ Ultra Breast Biopsy System probe for diagnostic sampling of tissue during a breast biopsy procedure.

Intended Use of Device:

The modified FINESSE™ Ultra Breast Biopsy System Driver is intended to obtain soft tissue samples for diagnostic and histological analysis of breast abnormalities.

Indications for Use of Device:

The FINESSE™ Ultra Breast Biopsy System is indicated to obtain tissue samples from the breast or axillary lymph nodes for diagnostic analysis of breast abnormalities. The instrument is intended to provide breast tissue for histologic examination with partial or complete removal of the imaged abnormality.

The extent of histologic abnormality cannot be reliably determined from its mammographic appearance. Therefore, the extent of removal of the imaged evidence of an abnormality does not predict the extent of removal of a histologic abnormality (e.g., malignancy). When the sampled abnormality is not histologically benign, it is essential that the tissue margins be examined for completeness of removal using standard surgical procedures

Technological Comparison to Predicate Devices:

The modified FINESSE™ Ultra Breast Biopsy System Driver is identical to the predicate devices in the following ways:

- Intended Use
- Indications for Use
- Target Population
- Fundamental Scientific Technology
- Operating Principle
- Driver Mechanical Design
- Performance Characteristics

The subject device and the predicate device are different in the following way:

- Software
  - Modifications to address errors resulting from out of alignment issues between driver and probe components. The software updates will allow the device to recover from non-clinically relevant errors and make the device easier to use.
  - Modification to allow use of the current IR port to update software

Performance Data:

The Modified FINESSE™ Ultra Breast Biopsy System Driver was evaluated via data collected from bench testing, and the data demonstrate that the Modified FINESSE™ Ultra Breast Biopsy System Driver is substantially equivalent to the predicate device. The testing performed was that which was identified during the Risk Assessment and Design Failure Modes and Effects Analysis.

Conclusions:

The Modified FINESSE™ Ultra Breast Biopsy System Driver met all acceptance criteria for design verification and validation, as specified by applicable standards, guidance, test protocols and/or customer inputs. The modified FINESSE™ Ultra Breast Biopsy System Driver is substantially equivalent to the legally marketed predicate device, the driver of the FINESSE™ Ultra Breast Biopsy System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

C. R. Bard, Inc.
Bard Peripheral Vascular, Inc.
% Ms. Cindy Moss
Regulatory Affairs Project Manager
1415 West Third Street
Tempe, Arizona 85281

DEC 27 2010

Re: K103359
Trade/Device Name: FINESSE™ Ultra Breast Biopsy System Driver
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: Class II
Product Code: KNW
Dated: December 15, 2010
Received: December 16, 2010

Dear Ms. Moss:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

DEC 2 7 2010

510(k) Number (if known): K103359

Device Name: FINESSE™ Ultra Breast Biopsy System Driver

Indications for Use: The FINESSE™ Ultra Breast Biopsy System Driver is indicated to obtain tissue samples from the breast or axillary lymph nodes for diagnostic analysis of breast abnormalities. The instrument is intended to provide breast tissue for histologic examination with partial or complete removal of the imaged abnormality.

The extent of histologic abnormality cannot be reliably determined from its mammographic appearance. Therefore, the extent of removal of the imaged evidence of an abnormality does not predict the extent of removal of a histologic abnormality (e.g., malignancy). When the sampled abnormality is not histologically benign, it is essential that the tissue margins be examined for completeness of removal using standard surgical procedures.

Prescription Use X AND/OR Over-The-Counter Use_____
(Part21 CFR 801 Subpart D) (21CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nick A. Pyle for MXM
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K103359